Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

_____/

ORDER GRANTING RETAILER AND PHARMACY DEFENDANTS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION, GRANTING DISTRIBUTOR DEFENDANTS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION, DENYING AS MOOT RETAILER AND PHARMACY DEFENDANTS' RULE 12 MOTION TO DISMISS ON STATE LAW GROUNDS, AND DENYING AS MOOT DISTRIBUTOR DEFENDANTS' RULE 12 MOTION TO DISMISS ON VARIOUS GROUP-SPECIFIC GROUNDS

This matter is before the Court on the Defendant Retailers' ("Retailer Defendants") Rule 12 Motion to Dismiss on the Grounds of Preemption [DE 1584], the Defendant Distributors' ("Distributor Defendants") (when referencing both Defendants, collectively "Defendants") Rule 12 Motion to Dismiss on the Ground of Preemption [DE 1583] (collectively, "Defendants' First Round Motions to Dismiss"), the Retailers' Rule 12 Motion to Dismiss on State Law Grounds [DE 2044], and the Distributors' Rule 12 Motion to Dismiss on Various Group-Specific Grounds [DE 2045] (collectively, "Defendants' Second Round Motions to Dismiss"). The Court held a hearing on the Motions to Dismiss on December 15, 2020 ("the Hearing"). The Court has carefully considered the Motions, the Responses [DE 1977,[1] 2243, 2244], the Replies [DE 2128, 2131, 2323, 2326], the Notice of Supplemental Authority [DE 2488], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons

[1] The Plaintiffs filed a consolidated Response to the Defendants' First Round Motions to Dismiss.

set forth below, the Defendants' First Round Motions to Dismiss are **GRANTED**, the Plaintiffs' claims are **DISMISSED**, and the Defendants' Second Round Motions to Dismiss are **DENIED AS MOOT**; the Plaintiffs shall have leave to amend a subset of their claims.[2]

I. Factual Background[3]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980's, first by prescription and later as an over-the-counter medication ("OTC"). In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster – the first prescription drug in history to reach $1 billion in sales. ¶ 231.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an OTC form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired

[2] To the extent the Defendants have requested any relief through incorporation of the Generic Defendants' Motion to Dismiss at docket entry 1582, the Court's ruling in its Order Granting Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption applies. To the extent the Defendants have requested any relief through incorporation of the Brand Defendants' Motion to Dismiss at docket entry 1580, the Court's forthcoming order on that Motion applies.

[3] A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor." (quotation marks omitted)). Plaintiffs have set forth their factual allegations in three "master" complaints: the Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 249-51.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, Plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February

6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, hundreds of Plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the Southern District of Florida. In addition, this Court has created a Census Registry where thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. MPIC ¶¶ 1, 6, 19. Plaintiffs allege that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. Plaintiffs are pursuing federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* Consolidated Consumer Class Action Complaint ("CCCAC"). The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motions to Dismiss pursuant to that schedule.

III. The Master Complaints

A. Master Personal Injury Complaint

All individuals who file a Short Form Complaint (collectively, the "MPIC Plaintiffs") adopt the MPIC. MPIC at 2.[4] The MPIC Plaintiffs allege that they developed cancers from taking the Defendants' ranitidine products. *Id.* at 1. The MPIC "sets forth allegations of fact and law common to the personal-injury claims" within the MDL. *Id.* at 1. Each MPIC Plaintiff individually seeks compensatory damages, punitive damages, restitution, and all other available remedies. *Id.* at 1-2.

The MPIC Defendants are entities that "designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine." *Id.* ¶ 20. They are categorized by the MPIC Plaintiffs into five groups: (1) Brand-Name Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; (4) Retailer Defendants; and (5) Repackager Defendants. Some MPIC Defendants belong to multiple categories.[5] Within each category, the MPIC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named MPIC Defendants.[6] Certain allegations apply to MPIC Defendants across multiple groups.[7]

The MPIC contains 15 counts: Strict Products Liability—Failure to Warn (Count I), Strict Products Liability—Design Defect (Count II), Strict Products Liability—Manufacturing Defect (Count III), Negligence—Failure to Warn (Count IV), Negligence Product Design (Count V),

[4] Unless noted otherwise, all page number references herein are to the page numbers generated by CM/ECF in the header of each document.
[5] For example, AmerisourceBergen is named as both a Generic Manufacturer Defendant and a Distributor Defendant. MPIC at 15 n.3.
[6] For example, CCCAC Defendant "Sanofi" refers to five entities: Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Sanofi S.A., Patheon Manufacturing Services LLC, and Boehringer Ingelheim Promeco, S.A. de C.V. MPIC ¶ 36.
[7] *See*, *e.g.*, MPIC ¶ 44 (allegations referring to Repackager Defendants apply to Ajanta, a Generic Manufacturer Defendant).

Negligent Manufacturing (Count VI), General Negligence (Count VII), Negligent Misrepresentation (Count VIII), Breach of Express Warranties (Count IX), Breach of Implied Warranties (Count X), Violation of Consumer Protection and Deceptive Trade Practices Laws (Count XI), Unjust Enrichment (Count XII), Loss of Consortium (Count XIII), Survival Actions (Count XIV), and Wrongful Death (Count XV). Counts I, II, IV, VII, IX, X, XI, XII, XIII, XIV and XV are brought against every MPIC Defendant. Counts V and VIII are brought against every Brand-Name Manufacturer, Generic Manufacturer and Repackager Defendant. Counts III and VI are brought against every Brand-Name Manufacturer and Generic Manufacturer Defendant.

B. Consolidated Consumer Class Action Complaint

One hundred and eighty-three named individuals (collectively, the "CCCAC Plaintiffs") bring the CCCAC on behalf of themselves and all others similarly situated.[8] The CCCAC Plaintiffs are citizens of nearly every state, the District of Columbia, and Puerto Rico. There are no CCCAC Plaintiffs who reside in or purchased ranitidine products from Delaware, Hawaii, Kansas, Maine, North Dakota, Rhode Island, or South Dakota. Each CCCAC Plaintiff asserts that he or she purchased and/or used a ranitidine product during an approximate timeframe.

The CCCAC Plaintiffs bring the action in their individual capacities and on behalf of numerous classes pursuant to Rule 23. Among the various classes are two nationwide classes: (1) the "RICO Class," comprised of "[a]ll residents of the United States or its territories who purchased for personal, family, or household use any of Brand-Name Manufacturer Defendants' Ranitidine-Containing Products in the United States or its territories"; and (2) the "Nationwide Class," comprised of "[a]ll residents of the United States or its territories who purchased and/or used for

[8] The CCCAC originally had 238 named plaintiffs, but 55 were subsequently dismissed without prejudice. *See* Order Granting Plaintiffs' Unopposed Motion to Drop Certain Plaintiffs from Consolidated Consumer Class Action Complaint, DE 2241.

personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories." CCCAC ¶ 734. The CCCAC alleges that as an alternative, and/or in addition to, the Nationwide Class, the CCCAC Plaintiffs bring the action in their individual capacities and on behalf of "State Classes" for all fifty states, the District of Columbia, and Puerto Rico. *Id.* ¶ 737. Each State Class is comprised of "[a]ll residents of [State or Territory] who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories." *Id.*

The defendants named in the CCCAC are entities that "invented, manufactured, distributed, labeled, marketed, advertised, . . . stored, and sold ranitidine." *Id.* ¶ 259. They are categorized by the CCCAC Plaintiffs into five groups: (1) Brand-Name Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; (4) Retailer Defendants; and (5) Repackager Defendants (collectively, the "CCCAC Defendants"). Some CCCAC Defendants belong to multiple categories. Within each category, the CCCAC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named CCCAC Defendants. Certain allegations apply to CCCAC Defendants across multiple groups.

The CCCAC alleges 314 counts against the CCCAC Defendants. The CCCAC Plaintiffs allege Count 1 (RICO) on behalf of the RICO Class against the Brand-Name Manufacturer Defendants. *Id.* ¶ 750. The CCCAC Plaintiffs allege Count 2 (unjust enrichment) and Count 3 (Magnuson-Moss Warranty Act) on behalf of the Nationwide Class against all CCCAC Defendants. *Id.* ¶¶ 795, 804. Alternatively, they bring Count 2 "on behalf of themselves under the laws of the state in which each [CCCAC] Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of a Class comprised of members from each [CCCAC] Plaintiff's respective state." *Id.* ¶ 795. The CCCAC Plaintiffs allege Count 4 (fraud) on behalf of the

Nationwide Class against the Brand-Name Manufacturer Defendants, the Generic Manufacturer Defendants, and the Repackager Defendants. *Id.* ¶ 823. Alternatively, they bring Count 4 "on behalf of themselves under the laws of the state in which each [CCCAC] Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of each State Class." *Id.* The CCCAC Plaintiffs allege Count 5 (negligence) and Count 6 (battery) on behalf of numerous State Classes against all CCCAC Defendants. *Id.* ¶¶ 839, 886. Finally, the CCCAC Plaintiffs allege Counts 7 through 314 (including breach of express and implied warranties; failure to warn; manufacturing defects; design defects; state consumer protection violations; deceptive trade practices; and medical monitoring) on behalf of the various State Classes against some or all of the CCCAC Defendants. *Id.* ¶¶ 906-5899.

IV. Summary of the Parties' Arguments

As to the Defendants' First Round Motions to Dismiss, the Defendants argue that all of the Plaintiffs' claims must be dismissed. They must be dismissed because the Plaintiffs' state-law claims are pre-empted by federal law and the Plaintiffs' sole federal claim must be dismissed without a state-law claim to support it. In Response, the Plaintiffs argue that their state-law claims are not pre-empted by federal law for two reasons. First, Supreme Court precedent supports the proposition that their claims are not pre-empted. Second, their claims are parallel with federal law—there is no conflict (and therefore no pre-emption) with federal law.

As to the Defendants' Second Round Motions to Dismiss, the Defendants argue that a subset of the Plaintiffs' claims must be dismissed because they are precluded by state law. In Response, the Plaintiffs argue that exceptions in state law permit their claims to go forward.

V. Summary of the Court's Rulings

The Court concludes that all of the Plaintiffs' state-law claims against the Defendants are pre-empted by federal law and, as a result, are dismissed. Without a state-law claim to support it, the Plaintiffs' sole federal claim is dismissed as well. The Court will permit the Plaintiffs to re-plead a general negligence claim, subject to certain rulings contained in this Order. Because the Court concludes that the Plaintiffs' claims are dismissed, the Defendants' Second Round Motions to Dismiss are moot.

VI. Standard of Review

Defendants move to dismiss all of the claims against them under Federal Rule of Civil Procedure 12(b)(6) based on the affirmative defense of federal pre-emption. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 619 (2011) (describing federal pre-emption as a drug manufacturer's affirmative defense). A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted). A "complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd en banc*, 764 F.2d 1400 (11th Cir. 1985).

VII. Analysis of the Defendants' First Round Motions to Dismiss

An understanding of the law that applies to drugs approved by the FDA is necessary to understand the arguments that the parties make in briefing the Motions to Dismiss. Before turning to the parties' arguments, the Court discusses key statutes and regulations that govern the FDA's regulation of drugs. The Court next addresses impossibility pre-emption and significant cases that have addressed impossibility pre-emption in the drug context. The Court then turns to the issues raised in the briefing: absolute liability, misbranding, negligence, and federal regulation of drug supply chains. For each issue, the Court reviews the arguments of the parties, any relevant allegations in the Master Complaints, and any additional, issue-specific law before providing the Court's analysis and conclusion on the issue.

A. Federal Regulation of Drug Products

The FDA regulates prescription and over-the-counter ("OTC") drugs under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.* ("FDCA"). The FDCA provides a process for the FDA to approve a new drug through a new drug application ("NDA") and a process for the FDA to approve a drug that is the same as a previously approved drug through an abbreviated new drug application ("ANDA"). *See* 21 U.S.C. § 355. A drug must have an FDA-approved NDA or ANDA to be introduced into interstate commerce. *Id.* § 355(a).

1. NDAs

An NDA must contain scientific data and other information showing that the new drug is safe and effective and must include proposed labeling. *See id.* § 355(b)(1). The FDCA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). The FDA may approve the NDA only if it finds, among other things, that the new drug is "safe for use under the

conditions prescribed, recommended, or suggested in the proposed labeling"; that there is "substantial evidence that the drug will have the effect it purports or is represented to have . . . in the proposed labeling"; that the methods and facilities for manufacturing, processing, and packaging the drug are adequate "to preserve its identity, strength, quality, and purity"; and that the labeling is not "false or misleading in any particular." *Id.* § 355(d). A drug approved under the NDA process, commonly referred to as a "brand-name drug," is "listed" by the FDA as having been "approved for safety and effectiveness." *See id.* § 355(j)(7). Following the approval of its NDA, a brand-name drug has a certain period of exclusivity in the marketplace. *See id.* § 355(j)(5)(F).

2. ANDAs

Subject to that period of exclusivity, a drug manufacturer may seek the approval of a drug that is identical in key respects to a listed drug by filing an ANDA. *See id.* § 355(j); *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 477 (2013) (explaining that a generic drug may be approved through the ANDA process "provided the generic drug is identical to the already-approved brand-name drug in several key respects"). A drug approved under the ANDA process is commonly referred to as a "generic drug." The ANDA must contain information showing that the generic drug has the same active ingredient(s), route of administration, dosage form, strength, therapeutic effect, and labeling as the listed drug and is "bioequivalent" to the listed drug. 21 U.S.C. § 355(j)(2)(A). With limited exceptions, the FDA may approve the ANDA only if it finds that the generic drug and its proposed labeling are the same as the listed drug and the listed drug's labeling. *See id.* § 355(j)(4); *see also* 21 C.F.R. § 314.94(a)(8)(iii), (iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug . . . ."). One such exception is that

the generic drug's proposed labeling "may include differences in expiration date" from the listed drug. 21 C.F.R. § 314.94(a)(8)(iv).

3. Changes to Drugs with Approved NDAs and ANDAs

The FDA also has requirements for when and how a drug manufacturer may change a drug or drug labeling that has an approved NDA or ANDA. *See id.* §§ 314.70, .97(a). These requirements differ depending on the category of change that the manufacturer seeks to make. However, despite the availability of these processes to make changes, "generic drug manufacturers have an ongoing federal duty of 'sameness'" that requires "that the warning labels of a brand-name drug and its generic copy must always be the same." *Mensing*, 564 U.S. at 613; *see also* 21 C.F.R. § 314.150(b)(10) (explaining that approval for an ANDA may be withdrawn if the FDA finds that the drug product's labeling "is no longer consistent with that for the listed drug"). Thus, the Changes Being Effected ("CBE") process allows "changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Mensing*, 564 U.S. at 614.

B. Impossibility Pre-emption

The Supremacy Clause of the U.S. Constitution provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "It is basic to this constitutional command that all conflicting state provisions be without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (citing *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819)). The pre-emption doctrine is derived from the Supremacy Clause. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

Supreme Court caselaw has recognized that state law is pre-empted under the Supremacy Clause in three circumstances. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). First, "Congress can define explicitly the extent to which its enactments pre-empt state law." *Id.* Second, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.* at 79. Third, state law is pre-empted "to the extent that it actually conflicts with federal law . . . where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citation and quotation marks omitted). Three key Supreme Court opinions have addressed impossibility pre-emption—a subset of conflict pre-emption—in the drug context.

1. *Wyeth v. Levine*

In *Wyeth v. Levine*, a consumer of a brand-name drug sued the brand-name drug manufacturer on negligence and strict-liability theories under Vermont law for failure to provide an adequate warning on the drug's labeling. 555 U.S. 555, 559-60 (2009). The Supreme Court held that the consumer's labeling claims were not pre-empted because the CBE process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the labeling, without waiting for FDA approval. *Id.* at 56869, 571, 573. The Court stated that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both its federal-law and state-law duties "absent clear evidence that the FDA would not have approved" a labeling change. *Id.* at 571. The brand-name drug manufacturer "offered no such evidence," and the fact that the FDA had previously approved the labeling did "not establish that it would have prohibited such a change." *Id.* at 572-73.

2. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, consumers of generic drugs sued the generic drug manufacturers under Minnesota and Louisiana tort law for failure to provide adequate warnings on the drugs' labeling. 564 U.S. at 610. The Supreme Court held that the consumers' labeling claims were pre-empted because the generic drug manufacturers could not "independently" change the labeling while remaining in compliance with federal law. *Id.* at 618-20, 623-24. The generic drug manufacturers' "duty of 'sameness'" under federal law required them to use labeling identical to the labeling of the equivalent brand-name drug. *Id.* at 613. Thus, the CBE process was unavailable to the generic drug manufacturers to change labeling absent a change to the brand-name drug's labeling. *Id.* at 614-15. Because any change that the generic drug manufacturers made to the drugs' labeling to comply with duties arising under state tort law would have violated federal law, the state tort claims were pre-empted. *Id.* at 618, 623-24.

The consumers argued, and the FDA asserted in an amicus brief, that even if the generic drug manufacturers could not have used the CBE process to change the labeling, the manufacturers could have "asked the FDA for help" by proposing a labeling change to the FDA. *Id.* at 616, 619. The consumers further argued that their state-law claims would not be pre-empted unless the generic drug manufacturers demonstrated that the FDA would have rejected a proposed labeling change. *Id.* at 620. The generic drug manufacturers conceded that they could have asked the FDA for help. *Id.* at 619.

The Supreme Court rejected the argument that the ability to ask the FDA for help defeated impossibility pre-emption. *Id.* at 620-21. The Court stated that the "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620 (citing *Wyeth*, 555 U.S. at 573). "[W]hen a party cannot satisfy its state duties without

the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-24. Asking the FDA for help "would have started a Mouse Trap game" that eventually may have led to a labeling change, "depending on the actions of the FDA and the brand-name manufacturer." *Id.* at 619-20. But, the Court stated, pre-emption analysis that was dependent on what a third party or the federal government might do would render impossibility pre-emption "all but meaningless." *Id.* at 620-21 ("If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.").

3. *Mutual Pharmaceutical Co. v. Bartlett*

In *Mutual Pharmaceutical Co. v. Bartlett*, a consumer of a generic drug brought a design defect claim under New Hampshire law against a generic drug manufacturer for failure to ensure that the drug was reasonably safe. 570 U.S. at 475. Under New Hampshire law, a drug manufacturer could satisfy its duty to ensure that its drug was reasonably safe "either by changing a drug's design or by changing its labeling." *Id.* at 482, 492. However, because the generic drug manufacturer was unable to change the drug's composition "as a matter of both federal law and basic chemistry," the only way for the manufacturer to fulfill its state-law duty and "escape liability" was by changing the labeling. *Id.* at 475, 483-84 (citing 21 U.S.C. § 355(j) for the proposition that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"). The Supreme Court concluded that, under *Mensing*, federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law,

that is, changing the labeling, and therefore the consumer's design-defect claim was pre-empted. *Id.* at 475, 486-87 (citing *Mensing*, 564 U.S. 604).

The First Circuit Court of Appeals had ruled that the generic drug manufacturer could comply with both federal and state law by removing the drug from the market. *Id.* at 475, 479. The Supreme Court stated that this was "no solution" because adopting this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in th[e] Court's pre-emption case law." *Id.* at 475, 488-90 (rejecting the stop-selling rationale as "incompatible" with pre-emption jurisprudence because, in "every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting"). Pre-emption caselaw "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488.

4. Application of *Mensing* and *Bartlett*

Based on the *Mensing* and *Bartlett* opinions, federal courts have held that numerous categories of claims against generic drug manufacturers are pre-empted, even where plaintiffs do not couch their claims as design defect or failure to warn. For example, courts have held that claims against generic drug manufacturers for failure to communicate information to consumers or medical providers, where the manufacturers of the listed brand-name drugs have not done so, are pre-empted. *See, e.g.*, *In re Darvocet*, 756 F.3d 917, 932-33 (6th Cir. 2014) (concluding that a claim that generic drug manufacturers should have sent letters explaining safety risks to medical providers was pre-empted because, "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading" (quotation marks omitted));

Lashley v. Pfizer, Inc., 750 F.3d 470, 47475 (5th Cir. 2014) (concluding that a claim that generic drug manufacturers should have communicated information consistent with the brand-name drug labeling was pre-empted because "the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead" (quotation omitted)); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (concluding that a claim that generic drug manufacturers should have communicated that a labeling change had been made was pre-empted because the manufacturers "were not at liberty" to communicate such information where "no brand-name manufacturer sent a warning based on the . . . label change").

Courts similarly have held that claims against generic drug manufacturers for failure to conduct testing of their drug products are pre-empted. *See, e.g.*, *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476-77 (4th Cir. 2014) (concluding that a claim that a generic drug manufacturer was negligent in the "testing, inspection, and post-market surveillance" of its drug product was pre-empted because any duty to perform such acts fell within the "general duty to protect consumers from injury based on the negligent marketing and sale of a product," and the manufacturer "whose product is unreasonably dangerous as sold could not satisfy that [general] duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability"); *Morris*, 713 F.3d at 778 (concluding that a claim that generic drug manufacturers failed to test and inspect their products was pre-empted, in part, because "any 'useful' reporting [of testing results]—at least from the standpoint of those injured—would ostensibly consist of some sort of warning," which the manufacturer could not give).

Courts also have held that claims against generic drug manufacturers for misrepresentation, fraud, and violation of consumer-protection statutes are pre-empted. *See, e.g.*, *In re Darvocet*, 756 F.3d at 935-36 (concluding that fraud, misrepresentation, and consumer-protection claims

against generic manufacturers were pre-empted because the claims "all challenge[d] label content," the plaintiffs did "not identify any representations made other than those contained in the FDA-approved labeling," and the manufacturers "could not have corrected any alleged misrepresentation without violating federal law because they were required to conform their labeling to that of the brand-name drugs"); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 680 (5th Cir. 2014) (concluding that consumer-protection claims against generic manufacturers were pre-empted because the claims were based on allegations that the manufacturers failed to sufficiently warn consumers, and federal law forbade the manufacturers from making any changes to their FDA-approved warnings); *Drager*, 741 F.3d at 479 (concluding that negligent misrepresentation and fraudulent concealment claims against a generic drug manufacturer were pre-empted because they were premised on the content of the labeling, the manufacturer had "no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or truthful," and the manufacturer's "only remaining options [were] to leave the market or accept tort liability").

As one final example, courts have held that claims against generic drug manufacturers for breaches of express and implied warranties are pre-empted. *See, e.g.*, *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013) (concluding that an express-warranty claim against a generic drug manufacturer was pre-empted because the plaintiffs did not identify a mechanism through which the manufacturer "could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness" and that claims for breach of the implied warranties of merchantability and fitness for intended use were pre-empted because the manufacturer "could not have altered the composition of the [drug] it manufactured without violating federal law"); *Drager*, 741 F.3d at 478-79 (concluding that claims that a generic drug manufacturer had breached

an express warranty and the implied warranties of merchantability and fitness for a particular purpose were pre-empted because the manufacturer could not have changed its warnings or drug formulation to comply with the warranties and therefore could avoid liability only by leaving the market).

C. Issues in the Defendants' First Round Motion to Dismiss

The Defendants contend that, under *Mensing* and *Bartlett*, all of the non-derivative claims against them in the MPIC and the CCCAC are pre-empted and must be dismissed. For their part, the Plaintiffs maintain that none of their claims are pre-empted. The parties' arguments revolve around four separate legal issues raised in the briefing: (1) absolute liability, (2) federal misbranding, (3) general negligence, and (4) the law applicable to prescription drug supply chains. The Court addresses each in turn before turning to (5) the Plaintiffs' federal claim and state-law derivative claims.

1. Absolute Liability

a. **Arguments and Allegations**

The Defendants argue that they do not have authority under federal law to alter a drug's design or label; all of the Plaintiffs' state-law claims are pre-empted under *Bartlett* and *Mensing* because, at their core, all of the Plaintiffs' state-law claims are based upon either an allegation of a faulty design or a faulty label. The Defendants cite to cases which found pre-emption where claims were based upon improper labeling and defective design—cases where the defendant had no ability to alter a label or alter a design. *E.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2:14-mn-02502-RMG, 2016 WL 7368203, at *2 (D.S.C. Nov. 1, 2016) ("a pharmacy also has no authority to unilaterally change a drug's label" and thus, any claims against the pharmacy based on the label are pre-empted); *Greager v. McNeil-PPC, Inc.*,

414 F. Supp. 3d 1137, 1142 (N.D. Ill. 2019) (dismissing claims against retail seller of OTC drug on pre-emption grounds). Indeed, courts have even found that claims against *brand manufacturers* were pre-empted when the manufacturer lost the ability to alter a label. *See In re Darvocet*, 756 F.3d at 940 (affirming dismissal of state claims against brand manufacturer as pre-empted because, once that defendant divested its NDA prior to plaintiff's use of the drug, that defendant had "no more power to change the [brand] label than did [the generic manufacturer]"); *see also Smith v. Teva Pharm. USA, Inc*., 437 F. Supp. 3d 1159, 1165-66 (S.D. Fla. 2020) ("The FDA's regulations nowhere contemplate a distributor of a brand drug, albeit a distributor closely affiliated with the NDA holder, initiating changes to an approved NDA . . . Fatal to Plaintiff's claims is that Defendant is not [the drug's] NDA holder.").

In contrast to the foregoing authority, the Plaintiffs have provided no citation to a case where similar claims against retailers (or distributors) survived a pre-emption analysis. Similarly, the Plaintiffs have provided no authority in direct opposition to the foregoing authority. Rather, the Plaintiffs respond that neither *Bartlett* nor *Mensing* apply to their claims because their claims are sourced in a theory of absolute liability under state law, while *Bartlett* and *Mensing* addressed only strict liability under state law. As the Plaintiffs argue that their claims impose absolute liability on the Defendants, they reference the first footnote in the *Bartlett* opinion: "We can thus save for another day the question whether a true absolute-liability state-law system could give rise to impossibility pre-emption." *Bartlett*, 570 U.S. at 482 n.1. Because *Bartlett* expressly declined to hold that absolute liability claims are pre-empted and since all of the Plaintiffs' claims allege absolute liability against the Defendants, the Plaintiffs argue that their claims survive under the *Bartlett* footnote. For their part, the Defendants argue that the Plaintiffs have not pled any absolute liability claims, nor could they as no state has recognized such a claim.

The Plaintiffs have not pled absolute liability claims. The word "absolute" does not appear once in the 1,523 pages of the MPIC and the CCCAC. At the Hearing, the Plaintiffs clarified that their position is that the Court should treat their strict liability claims as functionally equivalent to absolute liability claims. DE 2499 at 95 ("We think that all of these causes of action . . . sound in strict liability. . . . There is no such thing under state law so far as we know as a cause of action titled absolute liability . . . .").

b. Law on Absolute Liability

The Supreme Court in *Bartlett* squarely rejected the plaintiff-respondent's attempt to recast her strict lability claims as absolute liability claims:

> [R]espondent's argument conflates what we will call a "strict-liability" regime (in which liability does not depend on negligence, **but still signals the breach of a duty**) with what we will call an "absolute-liability" regime (**in which liability does not reflect the breach of any duties at all**, but merely serves to spread risk). New Hampshire has adopted the former, not the latter. Indeed, the New Hampshire Supreme Court has consistently held that the manufacturer of a product has a "duty to design his product reasonably safely for the uses which he can foresee." *Thibault v. Sears, Roebuck & Co.,* 118 N.H. 802, 809, 395 A.2d 843, 847 (1978). See also *Reid v. Spadone Mach. Co.,* 119 N.H. 457, 465, 404 A.2d 1094, 1099 (1979) ("In New Hampshire, the manufacturer is under a general duty to design his product reasonably safely for the uses which he can foresee" (internal quotation marks omitted)); *Chellman v. Saab–Scania AB,* 138 N.H. 73, 78, 637 A.2d 148, 150 (1993) ("The duty to warn is part of the general duty to design, manufacture and sell products that are reasonably safe for their foreseeable uses"); cf. *Simoneau v. South Bend Lathe, Inc.,*130 N.H. 466, 469, 543 A.2d 407, 409 (1988) ("We limit the application of strict tort liability in this jurisdiction by continuing to emphasize that liability without negligence is not liability without fault"); *Price v. BIC Corp.,* 142 N.H. 386, 390, 702 A.2d 330, 333 (1997) (cautioning "that the term 'unreasonably dangerous' should not be interpreted so broadly as to impose absolute liability on manufacturers or make them insurers of their products"). Accordingly, respondent is incorrect in arguing that New Hampshire's strict-liability system "imposes no substantive duties on manufacturers." Brief for Respondent 19.

Bartlett, 570 U.S. at 481-82 (emphases added). The Supreme Court rejected the plaintiff's contention that her strict liability claim imposed no duty on the defendant (serving instead only to

spread risk) and instead found that the defendant did owe a duty—there was no absolute liability, independent of a duty owed to a consumer. *Id.* at 485-86. Because the defendant's duty was to either redesign the drug or alter the label, and because both of those actions were prohibited by federal law, the Supreme Court held that the plaintiff's design defect claim was pre-empted. *Id.* at 486-87. Important to the instant case (and as bolded above), the Supreme Court clarified that an absolute liability theory is one that imposes no duties on a defendant. *Id.* at 481.

The Supreme Court's state-specific analysis in *Bartlett* considered the duties a generic manufacturer in New Hampshire owed to the consumers of its products. *Id.* at 481-82. In the abstract, the range of possible duties a state could impose upon a retailer (that merely sells a packaged product) is logically more constrained than the duties a state could conceivably impose upon a manufacturer that designs, produces, *and* sells a product. Unlike a manufacturer, a retailer's more limited duty is, essentially, not to sell a defective product—under such a duty, "[i]t is not enough to show that the product caused the plaintiff's injury or was involved in it. The plaintiff must show that there was something wrong with the product." *E.g., Tatum v. Cordis Corp.*, 758 F. Supp. 457, 461 (M.D. Tenn. 1991). The Supreme Court expressly expounded upon this concept in *Bartlett* when it refused to permit the plaintiff to equate strict liability with absolute liability. For authority in reaching its conclusion, the Court cited to the Restatement (Second) of Torts, Section 402A. The Restatement explains that a seller's duty under a strict liability regime is not to "sell[] any product in a defective condition." RESTATEMENT (SECOND) OF TORTS § 402A (Am. L. Inst. 1965).

The Plaintiffs have provided no authority for the proposition that the Defendants can be held liable in strict liability regardless of whether there was something wrong with a product or the product's label. At the Hearing, the Court asked Plaintiffs' counsel whether Plaintiffs were

aware of any state which would permit a jury trial without the Plaintiff having the burden of proof to show that something was wrong with ranitidine's design or label—the Plaintiffs answered in the negative. DE 2499 at 109-10.

Though strict liability "means liability without negligence, it does not mean liability without some type of fault. . . . There must be such a defect in the product as to render it unreasonably dangerous to the user." *Oregon Farm Bureau Ins. Co. v. E.L. Caldwell & Sons, Inc.*, 306 F. Supp. 835, 838 (D. Or. 1969). In the absence of fault—in the absence of a duty not to sell a *defective* product—a retailer would be relegated to the role of an insurer for each sale it makes and, for this reason, courts have refused to impose an absolute liability system under the auspices of strict liability. *See, e.g., Peterson v. Superior Ct.*, 899 P.2d 905, 919 (Cal. 1995) (rejecting "the function of loss spreading" as the sole rationale for imposing strict liability); *see also Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 559 (Cal. 1991) ("[I]t was never the intention of the drafters of the [strict liability] doctrine to make the manufacturer or distributor the insurer of the safety of their products. It was never their intention to impose *absolute* liability."); *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 199 (Ill. 1980) ("Strict liability is not the equivalent of absolute liability."); *Daly v. Gen. Motors Corp.*, 575 P.2d 1162, 1166 (Cal. 1978) ("From its inception, . . . strict liability has never been, and is not now, *absolute* liability.") (emphasis added); *McHargue v. Stokes Div. of Pennwalt*, 686 F. Supp. 1428, 1434 (D. Colo. 1988) ("Strict liability, however, is not the equivalent of absolute liability. . . .").

The Plaintiffs cite to two trial court decisions in Pennsylvania[9] decided by the same judge on the same day: *Hassett v. Dafoe*, 74 A.3d 202 (Pa. Super. Ct. 2013) and *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80 (Pa. Super. Ct. 2013). The Plaintiffs' citation is for the

[9] The Plaintiffs also analogize absolute liability to vicarious liability; these doctrines are plainly distinct, and vicarious liability is irrelevant to the issues before the Court.

proposition that Pennsylvania strict liability causes of action are not pre-empted under *Bartlett*. The cases, however, do not support the Plaintiffs' proposition. In contrast to the Plaintiffs' representation that *Hassett* held that *Bartlett* does not pre-empt strict liability claims against retailers under Pennsylvania law, the quote cited by the Plaintiffs merely sets forth what the plaintiffs' *argument* was in *Hassett*—the plaintiffs *argued* that *Bartlett* did not pre-empt Pennsylvania strict liability claims. The best support that can be found for the Plaintiffs in *Hassett* is that the trial court made a reference that the argument "appear[ed] to have some vitality." 74 A.3d at 213. What the *Hassett* court held, however, was that while the plaintiffs' claims "may be of the type held to be pre-empted in *Bartlett*," the court could not reach a conclusion "without a careful analysis of the applicable state law." *Id.* at 217. And, without that analysis, any conclusion on *Bartlett* pre-emption would be "premature." *Id.*

c. **Analysis and Conclusion**

The Court first considers whether *Bartlett* and *Mensing* facially apply and therefore preclude the Plaintiffs' claims. The Defendants' first point—any state-law claim based upon a faulty label is pre-empted—is supported by a plain reading of *Mensing*:

> To summarize, the relevant state and federal requirements are these: State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. . . . [T]his duty required the Manufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. . . . We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them.

564 U.S. at 617-18. Similarly, the Defendants' second point—any claim based upon drug design is pre-empted—is also supported by a plain reading of *Bartlett*:

> In the present case, however, redesign was not possible. . . . [T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based. 21 U.S.C. §§ 355(j)(2)(A)(ii)–(v) and (8)(B); 21 C.F.R. § 320.1(c). Consequently, the Court

> of Appeals was correct to recognize that "Mutual cannot legally make sulindac in another composition." 678 F.3d, at 37. Indeed, were Mutual to change the composition of its sulindac, the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce. See 21 C.F.R. § 310.3(h) (giving examples of when the FDA considers a drug to be new, including cases involving "newness for drug use of any substance which composes such drug, in whole or in part").

Bartlett, 570 U.S. at 483-84. Finally, the Defendants' third point—pre-emption cannot be avoided by arguing that a party could have ceased to sell a product—is squarely addressed in *Bartlett*. *Id.* The Court next considers whether the Plaintiffs' claims against the Defendants, as alleged, are indeed based upon a faulty label or design.

The Plaintiffs' first count in the MPIC, Failure to Warn (Strict Liability), alleges that the Defendants failed to warn the Plaintiffs of dangerous risks because the Defendants knew of dangerous risks and did not warn the Plaintiffs about the same. MPIC ¶ 460. The Plaintiffs allege that the labels were inadequate. *Id.* ¶ 467.

The Plaintiffs' second count, Design Defect (Strict Liability), alleges that the Defendants designed a defective product, the ranitidine molecule, and failed to provide proper warnings concerning the design defect. *Id.* ¶¶ 474, 486.

The Plaintiffs' fourth count, Negligence—Failure to Warn, alleges that the Defendants could have, at the time of manufacture, "provided warnings or instructions regarding the full and complete risks" of ranitidine because they knew that the product was dangerous. *Id.* ¶ 505.

The Plaintiffs' seventh count, General Negligence, alleges that the Defendants did not provide the public with accurate information about ranitidine, and that the Defendants did not provide appropriate warnings about the potential effects of ranitidine consumption. *Id.* ¶ 545.

The Plaintiffs' ninth count, Breach of Express Warranties, alleges that no Plaintiff would have consumed ranitidine, had the Defendants properly disclosed the risks associated with consumption. *Id.* ¶ 583.

The Plaintiffs' tenth count, Breach of Implied Warranties, alleges that ranitidine was not adequately tested or researched and that the ranitidine sold by the Defendants was not safe or fit for consumption. *Id.* ¶ 596.

The Plaintiffs' eleventh count, Deceptive Acts, alleges that the Defendants represented ranitidine to have benefits and qualities that it did not have. *Id.* ¶ 608. Plaintiffs further allege that ranitidine was deceptively designed, manufactured, distributed, and sold. *Id.* ¶ 610.

The Plaintiffs' twelfth count, Unjust Enrichment, alleges that the Defendants omitted disclosures that ranitidine consumption presented an unreasonable risk. *Id.* ¶ 631.

As for the CCCAC, the Plaintiffs' allegations mirror the allegations in the MPIC, and the CCCAC brings essentially the same counts (*see* CCCAC at 8-35) with one deviation—the CCCAC brings a federal claim against the Defendants, a claim under the Magnuson-Moss Warranty Act.[10]

The Court concludes that all of the Plaintiffs' state-law claims against the Defendants are based upon ranitidine's allegedly defective design and inadequate labels/warnings. This Court cannot disregard the holdings in *Bartlett* and *Mensing*. The Defendants have no ability to alter a label or alter a drug's design; thus, claims against them premised on labeling and design are pre-empted. Courts have routinely reached this conclusion over the years since *Bartlett* and *Mensing* were decided, and the Plaintiffs provide no authority to the contrary.

[10] The Plaintiffs' Magnuson-Moss Warranty Act claim is addressed in Section 5, *infra*. The CCCAC also raises a state-law battery claim that alleges the Defendants improperly promoted, advertised, marketed, distributed, and sold ranitidine. CCCAC ¶ 894.

A Defendant can take only limited steps to comply with state-law duties stemming from the sale of a federally-approved drug; it can (1) modify the label, (2) issue a non-label warning, (3) redesign the drug, or (4) stop selling the product. The Plaintiffs do not dispute that the Defendants would be powerless to cure a design defect in a drug, to make changes to the drug's label, or to issue other warnings without FDA approval. The Defendants would therefore have no recourse to avoid liability except to stop selling the drug altogether. But one thing that *Bartlett* made clear is that a "stop-selling" theory cannot be the basis on which a state law claim survives pre-emption. 570 U.S. at 488-91. For this reason, as well as others, courts dismiss design and label-based claims against any defendant that is powerless to alter a design or alter a label. *E.g., Smith*, 437 F. Supp. 3d at 1165 ("Whether Plaintiff's state-law claims as to [the defendant] are preempted is wholly dependent on whether Defendant had the authority to 'unilaterally' initiate changes to [the drug's] labels.").

The Plaintiffs have provided no citation to post-*Bartlett* authority where a court reached a different conclusion, nor have the Plaintiffs cited to a case where a court held that strict liability is equivalent to absolute liability—a proposition that *Bartlett* squarely rejected. Instead, the Plaintiffs rely upon Section 402A of the Restatement of Torts, quoting the provision of 402A that notes that a seller may exercise all possible care, but still be found liable under a strict liability claim. But the Supreme Court in *Bartlett* utilized 402A in reaching its conclusion that strict liability is *not* equivalent to absolute liability because strict liability, unlike absolute liability, still imposes a duty upon a seller—the duty not to sell a defective product. At the Hearing, the Court asked the Plaintiffs' counsel if the Plaintiffs were aware of any pharmaceutical case or MDL subsequent to *Bartlett* and *Mensing* that found a state-law strict liability claim had been stated against a retailer or distributor—the Plaintiffs were unable to provide any citation. DE 2499 at

123-24. In summary, all of the caselaw weighs in favor of a conclusion that the Plaintiffs' claims are pre-empted. For these reasons, and because all of the Plaintiffs' state-law claims against the Defendants are premised upon the contention that ranitidine's design or label were deficient, all of the Plaintiffs' state-law claims against the Defendants are pre-empted and therefore dismissed.

The Court's dismissal is with prejudice and without leave to amend. The Court may deny leave to amend when further amendment would be futile. *E.g., Hall v. United Ins. Co. of Am*, 367 F.3d 1255, 1263 (11th Cir. 2004). The Defendants represent to the Court that there is no state that has imposed upon retailers or distributors a faultless, absolute-liability system wherein Defendants *do* function as insurers for damages flowing from the products that they sell. The Court's own research has similarly revealed no such state. At the Hearing, Plaintiffs' counsel conceded that he was not aware of any state that permitted a claim for absolute liability against a retailer or distributor. DE 2499 at 94-95. Instead, counsel affirmed that it was the Plaintiffs' position that their strict liability claims were equivalent (sounded in) absolute liability. *See id.* The Court therefore concludes that further amendment of claims predicated on design defect or an improper label would be futile and denies leave to amend for that reason; however, the Court will permit amendment as to Count VII, general negligence, for the reasons discussed below in subsection (3).

2. Federal Misbranding

a. Arguments and Allegations

The Plaintiffs argue that their claims are not pre-empted under *Bartlett* and *Mensing* because their claims are parallel to federal law—that is, there is no conflict between federal duties and state duties because the duties are, essentially, the same. They argue that (i) federal law prohibits the sale of misbranded drugs; (ii) the Plaintiffs have alleged that the Defendants sold misbranded drugs; and (iii) such misbranding is prohibited by state law. Thus, the Plaintiffs'

"misbranding" claim is a parallel claim—not a conflicting claim. The Defendants contend that the Plaintiffs' misbranding argument has never been accepted by a court and, if it were, such an argument would invalidate all existing Supreme Court precedent on impossibility pre-emption.

The Plaintiffs have not pled a standalone state-law misbranding claim. Rather, the Plaintiffs have incorporated the allegation that ranitidine was misbranded under federal misbranding law into each of their counts. *E.g.,* MPIC ¶ 418. The Plaintiffs allege that ranitidine products were misbranded because the Defendants "did not disclose NDMA as an ingredient" in the products, "did not disclose the proper directions for storage" of the products, and "did not disclose the proper directions for expiration" of the products. *Id.* ¶¶ 421-23; CCCAC ¶¶ 601-03.

b. Federal Statutes on Misbranding

The U.S. Code prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded," the "adulteration or misbranding of any . . . drug . . . in interstate commerce," the "receipt in interstate commerce of any . . . drug . . . that is adulterated or misbranded," and the "manufacture within any Territory of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a)-(c), (g). The Plaintiffs do not have a private cause of action to enforce this statute. *Id.* § 337(a) (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (explaining that "no private right of action exists for a violation of the FDCA"). Section 352 of the U.S. Code contains several sub-sections delineating the circumstances under which a drug "shall be deemed to be misbranded." 21 U.S.C. § 352. As relevant here, a drug is misbranded if "its labeling is false or misleading in any particular" or if "it is dangerous to health when used in the dosage or manner,

or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." *Id.* § 352(a)(1), (j).

c. Analysis and Conclusion

As a threshold matter, the Plaintiffs have not provided specific authority for the proposition that any of their state-law claims are parallel to federal misbranding law. Plaintiffs' theory of misbranding is that ranitidine's labeling was false and misleading (in violation of 21 U.S.C. § 352(a)(1)) and was dangerous to health when used in conformity with its labeling (in violation of 21 U.S.C. § 352(j)). The Plaintiffs' misbranding argument fails for several independent reasons.

First, as previously discussed, the Defendants could not correct the alleged misbranding by altering the composition of the drug, nor could the Defendants alter the drug's label. The Defendants would have no recourse but to stop selling the drug altogether which they are not required to do to comply with a state law duty. *Bartlett*, 570 U.S. at 488-91. The Plaintiffs' argument that federal law would require the Defendants to stop selling misbranded drugs is of no moment because the Plaintiffs have not plausibly alleged that the Defendants *knew* that the drugs were misbranded or otherwise could have detected the alleged defects in the ranitidine molecule.

Second, in the aftermath of *Bartlett*, courts have only entertained the possibility of misbranding-based claims when the claims were "pure design-defect claims." *E.g., In re Yasmin and Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2015 WL 7272766, at *4 (S.D. Ill. Nov. 18, 2015) (determining that the plaintiff could not "assert a 'pure' design defect claim under Illinois law."). By definition, however, such a claim could only be brought against a manufacturer—not a retailer or a distributor. *E.g.*, *In re Darvocet,* 756 F.3d at 929-30. Furthermore, the Plaintiffs have provided no authority for the proposition that pre-emption can be avoided by showing that a drug is misbranded under federal law.

Third, a finding that Plaintiffs can avoid pre-emption by alleging that defects in ranitidine products made the products misbranded under 21 U.S.C. § 352 would render the vast body of pre-emption caselaw in the drug context, including binding Supreme Court decisions, meaningless. If Plaintiffs' position were accepted, a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was "false or misleading in any particular" or that the drug was "dangerous to health when used" as prescribed. *See* 21 U.S.C. § 352(a)(1), (j). The Court cannot adopt a position that would render pre-emption caselaw meaningless. *Cf. Bartlett*, 570 U.S. at 488-90 (rejecting the stop-selling rationale because it was "incompatible with our pre-emption jurisprudence," would mean that the vast majority or all "of the cases in which the Court has found impossibility pre-emption, were wrongly decided," and would make impossibility pre-emption "all but meaningless" (quotation marks omitted)); *Mensing*, 564 U.S. 620-21 (rejecting the proposition that pre-emption analysis could be dependent on what a third party or the federal government might do because such a position would "render conflict pre-emption largely meaningless").[11] This is a topic addressed in the Court's Order Granting Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption. The Court adopts and incorporates herein the Court's analysis and conclusions contained in that Order.

Fourth, there is no private right of action to enforce federal misbranding law—a statute that imposes criminal penalties. *Ellis*, 311 F.3d at 1284 n.10. The Plaintiffs cannot create a private right of action to enforce federal misbranding rules by disguising it as a state-law strict-liability

[11] The Defendants raised an additional argument in support of their contention that the Plaintiffs' claims are pre-empted, an argument premised upon a good-faith exception contained in the federal misbranding statute, 21 U.S.C. § 333 ("No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith. . . ."). At the Hearing, the Plaintiffs made a counterargument that the good-faith exception does not apply in this case. DE 2499 at 75. Because the Court concludes that the Plaintiffs' misbranding argument does not apply for other, independent reasons, the Court need not address the Defendants' good-faith exception argument.

claim. Indeed, the Plaintiffs have represented that there *are no* state-law duties as to the Retailer Defendants.[12] DE 1977 at 12 (Section II.A. titled: "Retailers Have no Legal Duties Under State Law."). State tort claims that rely solely upon federal law for the source of a duty are pre-empted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

For the reasons set forth above, the Plaintiffs' state-law claims, other than the general negligence claim, against the Defendants are pre-empted and, therefore, dismissed with prejudice. The Court's dismissal is without leave to amend as further amendment would be futile; however, the Court will permit amendment as to Count VII, general negligence.

3. General Negligence

a. Arguments and Allegations

The Court concluded, in Section VII.C.1.c, that the Plaintiffs' general negligence claim, Count VII in the MPIC, was based upon the adequacy of ranitidine's design and label and, as a result, Count VII was dismissed as pre-empted. The Court's dismissal was without leave to amend; however, the Plaintiffs have separately argued (outside of the arguments contained in Section VII.C.1) that Count VII is unique—that it is not based upon the adequacy of a label or drug design. Thus, the Plaintiffs argue that Count VII is not pre-empted under *Bartlett* or *Mensing*. For their part, the Defendants contend that Count VII is not based upon any legally viable theory.

As pled, the General Negligence count is very broad. By way of example, the Plaintiffs have facially alleged that all of the Defendants *designed* ranitidine because neither the Retailer Defendants nor the Distributor Defendants are delineated from "Defendants" in Count VII. MPIC ¶ 543 ("Defendants, directly or indirectly, designed, manufactured, tested, marketed, labeled,

[12] Because the Plaintiffs filed a consolidated Response to both the Retailer and the Distributor Defendants, it may easily be inferred from the Plaintiffs' argument on this point that it is their contention that state law imposes no duties on *both* the Retailer Defendants and the Distributor Defendants.

packaged, handled, distributed, stored, and/or sold ranitidine-containing products that were used by the Plaintiffs."). Thus, the Plaintiffs allege that every Defendant in this MDL engaged in every possible action—designing, marketing, testing, labeling, packaging, and manufacturing—regardless of the individual Defendant's role or purpose in this case. *Id.* Additionally, not only is Count VII styled against all Defendants without delineation by any one Defendant's role, but the Count applies across every possible timeframe, running from the early 1980's to the present. *E.g.*, *id.* ¶ 542.

b. Analysis and Conclusion

The Court is required to view all factual allegations in the light most favorable to the Plaintiffs, *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1273 n.1 (11th Cir. 1999), but because of the Plaintiffs' shotgun-style pleading of Count VII, the Court cannot discern the precise factual grounds upon which Count VII is based. The Court has therefore relied upon the Plaintiffs' representations in their Response as to the underlying factual premise for Count VII to discern what the Count is intended to allege. The Plaintiffs devote only two paragraphs in their Response to explain the basis for Count VII as follows:

> The Complaints allege negligence against all Defendants. For example, the MPIC includes negligent failure to warn (Count IV) and general negligence (Count VII). The MPIC details a variety of ways in which temperature, light, and other factors relating to storage and handling can hasten ranitidine's breakdown into NDMA, and alleges that "[n]othing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws." MPIC ¶ 408. The FDA in fact requires that storage conditions be appropriate. *See* 21 C.F.R. § 211.142(b) (requiring "Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected").
>
> Defendants entirely ignore these negligence allegations. Instead, they mischaracterize all the claims as sounding entirely in failure to warn and design

> defect. *See* Retailer Mot. At 6 (glossing Count VII as entirely about warnings and marketing). Defendants have provided no basis to dismiss the negligence counts.

DE 1977 at 21-22.[13]

The Court draws two conclusions from the Plaintiffs' representation of the factual premise for Count VII. First, the Plaintiffs did intend for Count VII to be based, at least in part, on the adequacy of the ranitidine label and the alleged defective design of the drug. *See id.* at 22 ("Instead, [the Retailer Defendants] mischaracterize all of the claims as sounding *entirely* in failure to warn and design defect.") (emphasis added). The Court infers from the word "entirely" that, at least in part, Count VII sounded in failure to warn (a label-based claim) and design defect. This is why, in Section VII.C.1.c, the Court found Count VII to be pre-empted and dismissed the Count pursuant to *Bartlett* and *Mensing*.

The second conclusion that the Court draws is that the Plaintiffs also intended to premise Count VII on the concept of temperature, alleging that nothing "prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport." *Id.* The Court therefore addresses this temperature-based negligence theory.

The Plaintiffs have alleged that heat can cause the ranitidine molecule to rapidly break down into cancer-causing NDMA. MPIC ¶¶ 340-45. The Plaintiffs further allege:

> Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA. FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the

13 Because Count IV, negligent failure to warn, turns on the adequacy of the ranitidine label, that count is pre-empted for the reasons set forth in this Order.

> drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.
>
> Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

Id. ¶¶ 407-08 (footnote omitted). Thus, it is the Plaintiffs' contention that the Defendants should be held liable under state law because the Defendants should have used "cooled storage and transport." *Id.* ¶ 408. At the Hearing, the Court inquired about this allegation. *See* DE 2499 at 40-50. Plaintiffs' counsel responded that the Defendants could be held liable for not cooling ranitidine to a low-end-of-the-range temperature permitted by the ranitidine label. *Id.* at 47. Such an action, the Plaintiffs argued, would be consistent with federal regulation and therefore would impose no impossibility pre-emption on a Defendant.[14] The Plaintiffs also responded by explaining that they believed a Defendant could be held liable for overheating a drug in its possession, such as "le[aving] Ranitidine on a hot truck in the Arizona desert during the summer for extensive periods of time creating temperature ranges that vastly exceeded those on the label." *Id.* at 77. Neither of these theories is pled in the Master Complaints.

With respect to the "heating" theory—that the Defendants should be held liable for storing ranitidine at an elevated temperature prohibited by *both* federal law and state law—the Plaintiffs have leave in an amended complaint to plead this theory because, at this juncture, the Court is not prepared to conclude it would be futile for the Plaintiffs to so plead; this theory also received minimal discussion in the parties' briefing. Nonetheless, should the Plaintiffs proceed with this theory, the Plaintiffs should address the Court's concerns.

[14] At the Hearing, the Plaintiffs conceded that if a state law required a party to store ranitidine at a temperature *below* federally-approved storage conditions, impossibility pre-emption would apply. DE 2499 at 112.

Can the Plaintiffs plead in good faith that any Defendant had a *policy* to store ranitidine products at temperatures above those approved by the FDA? The Court has serious reservations as to whether the Plaintiffs can plead that the Defendants had a global policy or practice to do so because, presumably, that would mean that the Defendants stored *all* drugs—not just the drugs that are the subject of this MDL—at temperatures that could subject the Defendants to litigation from complications arising from all of the stored drugs in their possession. The more reasonable inference from the Plaintiffs' allegations in this regard is that, perhaps, individual stores or warehouses or trucks negligently stored ranitidine, but this leads the Court to additional concerns.

If *individual* stores negligently stored ranitidine at unsafe, heated temperatures, how is that a global, MDL-based issue? This scenario was implicated in the Plaintiffs' hypothetical, discussed at the Hearing, of a rogue truck overheating ranitidine in a desert. *Id.* That hypothetical appears to the Court to be both individualized and fact-specific and likely would have little, if any, bearing on the broader, more global questions in this MDL. This raises a question as to whether, if a specific truck overheated ranitidine in a desert, such a claim is appropriate in this MDL or should it be severed from the MDL. By way of example, medical malpractice actions are sometimes severed from MDL suits against pharmaceutical companies[15] because the individual questions posed by such claims are best addressed outside of an MDL. This MDL was created for the purposes of efficiency, and there is efficiency in adjudicating the common questions of law and fact stemming from the Plaintiffs' allegations that ranitidine was defectively designed and defectively labeled, together with the related causes of actions that flow from that allegation. DE 1 at 2. However, whether or not a specific truck broke down in a desert, contaminating the drugs contained in the truck, would not appear to be a common question of fact in this MDL.

[15] *E.g., Joseph v. Baxter Int'l Inc.*, 614 F. Supp. 2d 868, 870 (N.D. Ohio 2009).

Furthermore, do the causation questions inherent in a high-temperature allegation further suggest that severance would be appropriate? Suppose a plaintiff alleged that a specific store did not use appropriate air conditioning and, as a result, the ranitidine in the store generated NDMA which caused the plaintiff cancer. A natural, logical defense by the store may be that the overheating occurred prior to the store's receipt of the drug—perhaps by an overheated delivery truck or a manufacturer's overheated storage facility. Investigation where, in a supply chain, overheating occurred appears to the Court to be an individualized, fact-intensive discovery challenge. Each supply chain, perhaps even each shipment of ranitidine, could pose different fact-intensive questions—none of which concern global, MDL-based matters.

Finally, how is a high-temperature allegation consistent with the Plaintiffs' core theory of the case? At present, the central premise of this MDL is that ranitidine was defectively designed and that the problems with the ranitidine molecule were concealed from the FDA—the FDA did not know about the potential problems of the ranitidine molecule when the drug was approved for sale. Viewed in that light, how are high-temperature allegations to be squared with the Plaintiffs' theory of the case? Stated differently, it is the Plaintiffs' theory that the Plaintiffs' harm was caused at the very moment ranitidine was manufactured—the Plaintiffs have not alleged that, for some period of time, the ranitidine molecule was safe to consume but, because the Defendants negligently overheated the drug, the drug became unsafe to consume and therefore caused injury to a Plaintiff. This matter is also addressed in the Court's Order Granting Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption. Should the Plaintiffs

proceed with a high-temperature theory, the Plaintiffs must explain how that *specific* theory of liability is compatible with the Plaintiffs' *global* theory of liability.[16]

With respect to the Plaintiffs' "cooling" theory—that to the extent it is the Plaintiffs' intent to hold the Defendants liable for not storing ranitidine at the low-end of a federally-approved range—the Plaintiffs have leave to plead this theory in an amended complaint because, at this juncture, the Court is not prepared to conclude that it would be futile for the Plaintiffs to so plead; this theory received minimal discussion in the parties' briefing. Nonetheless, should the Plaintiffs proceed with this theory, the Plaintiffs should address the Court's additional concerns. How can a Defendant be found liable for storing a drug in accordance with a drug's label? The FDA drug approval process is what determines the appropriate storage temperature for a drug and, as conceded by the Plaintiffs, it is the manufacturer that determines proper storage procedures—not the Defendants. MPIC ¶ 412 (citing USP Ch. 1079). The Plaintiffs should provide authority for the proposition that (i) if a federally-approved label permits a party to store a drug at a specific temperature, nonetheless (ii) a state may impose liability for storing a drug at that temperature.

How were the Defendants to arrive at the conclusion that they should store ranitidine at the low-end of a federally-approved range? As the Plaintiffs concede in the MPIC, the duty to conduct scientific testing on drugs belongs to manufacturers, not retailers. *Id.* ¶ 370 (citing 21 C.F.R. § 211.166(a)). The Plaintiffs have provided no authority for the proposition that Defendants had a duty under state law to hire independent scientists to determine where, in a federally-approved temperature range, a drug should be stored. Finally, if the Plaintiffs challenge the appropriateness of the upper-range of a federally-approved label, does that amount to the charge that Defendants

[16] As explained in the Court's Order Granting Generic Manufacturers' and Repackagers Rule 12 Motion to Dismiss on the Ground of Preemption, the Plaintiffs may plead inconsistent, incompatible theories in the alternative, but the Plaintiffs have not yet done so.

may have a burden, imposed by state law, to deviate from the conditions *permitted* on a federally-approved label?

In conclusion, although the Court in Section VII.C.1.c dismissed all of the Plaintiffs' state-law claims without leave to amend on pre-emption grounds, the Court carves out one exception from its ruling for Count VII, general negligence. The Plaintiffs may amend Count VII, provided the amended claim is not based upon (i) the adequacy of an FDA-approved label or (ii) the design of ranitidine, as more fully discussed in this Order. The Plaintiffs may also amend any general negligence claims raised in the CCCAC. However, to the extent it is possible to do so, the Plaintiffs' amendment and future briefing on this subject should be responsive to the Court's concerns outlined above.

4. Prescription Drug Supply Chain

a. Arguments and Allegations

In addition to arguing impossibility pre-emption under *Bartlett* and *Mensing*, the Defendants argue an express pre-emption affirmative defense that applies to the Defendants that functioned as pharmacies and/or sold prescription-strength ranitidine. The Defendants argue that the Drug Supply Chain Security Act (the "Security Act" or "Act"), 21 U.S.C. §§ 360eee to 360eee-4, expressly pre-empts the Plaintiffs' claims. The Plaintiffs argue the Act is inapplicable to their claims because the Act only concerns product tracing, not product safety.

b. The Drug Supply Chain Security Act

In 2013, Congress passed the Security Act in an effort to secure the supply chain for prescription pharmaceutical drugs. The Act is intentionally broad and comprehensive, governing all trading partners (whether manufacturers, repackagers, distributors, or pharmacies) in the supply chain for prescription drugs and establishing a framework for the critical steps necessary to enable

the eventual electronic identification and traceability of prescription drugs. For example, since 2015, trading partners have been required to include specific transaction information for most transfers to other trading partners in the supply chain. *See id.* § 360eee-1.

The Act also imposes specific obligations on pharmacies, called "dispensers" in the Act's text. First, pharmacies may not accept ownership of a prescription drug unless the previous owner provides specific information about that drug, including its name, its strength and dose, and the manufacturer's confirmation that the drug is what it purports to be and is fit for distribution. *Id.* §§ 360eee(26)-(27), 360eee-1(d)(1)(A)(i). A pharmacy must reject any shipment that is missing this information. Second, the Act requires that pharmacies capture various information "as necessary to investigate a suspect product." *Id.* § 360eee-1(d)(1)(A)(iii) (requiring capture of, among other things, transaction history, product name and dose, and manufacturer's verification of product legitimacy). Suspect products include any drug that a pharmacy has reason to believe is adulterated or otherwise unfit for distribution. *Id.* § 360eee(21). Finally, pharmacies must implement a system for quarantining suspect products and determining whether they are unfit for distribution. *Id.* § 360eee-1(d)(4). Through this web of requirements for pharmacies and others in the supply chain, the Act creates a comprehensive, national framework that sets pharmacies' requirements for identifying, tracing, and isolating adulterated or misbranded drugs.

To give the Act effect, Congress included an express pre-emption provision that precludes imposition of any state requirement that is "inconsistent with, more stringent than, or in addition to" requirements under the Act, including investigation relating to systems for tracing misbranded or adulterated drugs. *Id.* § 360eee-4(a). The pre-emption provision provides uniformity so that trading partners are not subjected to different rules for identifying, tracing, and quarantining suspect products. It reads, in relevant part:

> *[N]o State or political subdivision of a State may establish or continue in effect any requirements* for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) *which are inconsistent with, more stringent than, or in addition to, any requirements applicable under [the Act]*.

Id. (emphases added). Unlike other express pre-emption provisions, which pre-empt only those state requirements that are "inconsistent" with federal standards, the Drug Security Act additionally pre-empts any state requirements for product tracing that are "more stringent than, or in addition to" federal requirements. *Cf. Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459-60 (2012) (Federal Meat Inspection Act's pre-emption clause that prevents a state from imposing any additional or different requirements "sweeps widely").

c. Analysis and Conclusion

For authority that the Act only concerns itself with drug tracing, the Plaintiffs rely upon the following block-quote in the Act focusing particularly on the bolded section of the quote:

> Beginning on November 27, 2013 [date of enactment], no State or political subdivision of a State may establish or continue in effect any requirements **for tracing products through the distribution system** (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable [by regulation or this statute].

DE 1977 at 18 (quoting 21 U.S.C. § 360-eee(4)(a)). The Plaintiffs ignore, however, additional text in the statute. The Act also pre-empts requirements pertaining to transaction statements, verification, *investigation*, or record keeping, as follows:

> Beginning on November 27, 2013 [date of enactment], no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (**including any requirements with respect to statements** of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, **or verification, investigation, disposition, notification, or recordkeeping relating to such systems**, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) **which are inconsistent with, more stringent than, or in addition to, any requirements applicable** [by regulation or this statute].

21 U.S.C. § 360-eee(4)(a) (emphases added). Thus, not only does the Act pre-empt state requirements that pertain to investigation or verification of drugs in the supply chain, but also any state law requirement that is inconsistent with, more stringent than, or in addition to, the requirements of the Act. As to these words—verification and investigation—the Plaintiffs' Response is silent.

The Act prohibits a pharmacy from accepting drugs unless certain criteria are met. *Id.* § 360eee-1(d)(1)(A)(i). But the Plaintiffs' theory of the case is that the Defendants that operated as pharmacies[17] should have refused to accept ranitidine on grounds in addition to—not contained in—the Act. The Plaintiffs contend that the Defendants should not have accepted ranitidine because it was defectively designed, the warning label was insufficient, and the drug may have produced NDMA during transport. The Plaintiffs respond to the Defendants' arguments that, even if there were a duty by the pharmacies to reject shipments of ranitidine, that duty has nothing to do with "tracing products through the distribution system." DE 1977 at 18-19.

In a Notice of Supplemental Authority, the Plaintiffs cite to a recent decision in an MDL wherein the Act was found not to pre-empt certain claims. DE [2488] (citing *In re Valsartan,*

[17] The Plaintiffs' Master Complaints do not contain a category for "Pharmacy Defendants." Nonetheless, the Defendants who have operated as pharmacies (at any point in time) have moved for dismissal to the extent any claim is premised upon the sale of prescription ranitidine. *See* Section VII.C.3 (discussing how the Plaintiffs have alleged that every Defendant in this MDL is liable for every action at every point in time).

Losartan, and Irbesartan Prods. Liab. Litig., No. 19-MD-02875, 2020 WL 7418006, at *10-11 (D.N.J. Dec. 17, 2020)). In *Valsartan*, the district court found that both the plaintiffs and the defendants had valid arguments in favor and against pre-emption under the Act, but the court ultimately held in favor of a finding of no pre-emption. 2020 WL 7418006, at *10-11. Unlike the instant case, however, in *Valsartan* the allegation was that the drug became contaminated *before* it entered the supply chain, not *within* the supply chain. *Id.* at 11.[18] Here, the Court declines to rule on pre-emption under the Act for two reasons.

First, the Court finds that it is unnecessary to decide whether the Act pre-empts claims against Defendants that operated as pharmacies and/or sold prescription-strength ranitidine where the Court has already found pre-emption as to *all* Defendants. Second, the Court declines to decide whether the Act applies to the Plaintiffs' claims when it does not, at this juncture, have clarity as to the precise scope of some of the Plaintiffs' claims. As discussed above in subsection (3) on general negligence, the Plaintiffs advanced a theory at the Hearing that the Defendants should be held liable for failing to cool ranitidine to temperatures at the low-end of the federally-approved range. If Plaintiffs plead and proceed with such a theory, it may be that the Plaintiffs' claims *are* based upon product tracing and are therefore pre-empted.

5. The Plaintiffs' Remaining Claims

The Plaintiffs' sole federal claim, a claim under the Magnuson-Moss Warranty Act, requires a valid state-law anchor breach of warranty claim, however, all of the Plaintiffs' state-law warranty claims have been dismissed. *Cardenas v. Toyota Motor Corp.*, 418 F. Supp. 3d 1090, 1110-11 (S.D. Fla. 2019); *Hernandez v. Johnson & Johnson Consumer, Inc.*, No. 3:19-cv-15679-

[18] The Plaintiffs have alleged that NDMA formed in ranitidine during normal, routine transport of the drug. *See* MPIC ¶¶ 407-08.

BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020). As a result, the Plaintiffs' federal warranty claim is dismissed without prejudice as to the Defendants.

Counts XIII, XIV, and XV of the MPIC are claims for loss of consortium, damages to be paid to the estates of deceased ranitidine-product consumers, and wrongful death. MPIC ¶¶ 637-56. Defendants refer to these three counts as "derivative" claims and contend that these claims must be dismissed if all of the other claims against them are dismissed. Plaintiffs do not dispute that the derivative claims must be dismissed if no other claims remain against Defendants, but Plaintiffs assert again that they can proceed with all of their claims against Defendants. *See In re Darvocet*, 756 F.3d at 936 (affirming a district court's dismissal of "derivative claims for wrongful death, survivorship, unjust enrichment, loss of consortium, and punitive damages" when the district court had dismissed all "underlying claims" because the derivative claims "stand or fall with the underlying claims on which they rest"). Because the Court is dismissing all underlying claims against Defendants for the reasons given herein, the derivative claims raised against Defendants in Counts XIII, XIV, and XV of the MPIC and any identical claims in the CCCAC are dismissed without prejudice.

VIII. Defendants' Second Round Motions to Dismiss

Pursuant to the Court's schedule in Pretrial Order # 36, the Defendants were permitted to file a second round of motions to dismiss, provided the second-round motions were limited to certain topics outlined in the Pretrial Order. The Defendants elected to file additional motions to dismiss that complied with Pretrial Order # 36. Defendants argue in those motions that, in the alternative to a finding by the Court that the Plaintiffs' claims are pre-empted by federal law, the Court should find that certain states have liability shields that insulate the Defendants from the Plaintiffs' claims. Because the Court has granted the Defendants' First Round Motions to Dismiss

on pre-emption grounds, the Court denies the Defendants' Second Round Motions to Dismiss as moot,[19] however, the Court addresses one specific point raised in the parties' briefing on the motions.

Both Second Round Motions to Dismiss argued that *some* states shield the Defendants from liability, but the Defendants' arguments were not broken out state-by-state. The Plaintiffs, in their Responses, argued that the Defendants had not met their burden to dismiss the claims in their entirety because the Defendants had not addressed the laws of each state. The Court recognizes that the Defendants' ability to make a state-by-state argument was impaired by the Plaintiffs' shotgun-style pleading. Plaintiffs shall clearly specify, in any future amended pleading, which states' laws their claims are brought under and, as a result, any future motions to dismiss raising the arguments in the second round of motions to dismiss should address the law applicable to the Plaintiffs' claims on a state-by-state basis.

IX. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Retailer Defendants' Motion to Dismiss at docket entry 1584 is **GRANTED** and the Distributor Defendants' Motion to Dismiss at docket entry 1583 is **GRANTED**. All of the Plaintiffs' claims against the Retailer and the Distributor Defendants are **DISMISSED**. The Court's dismissal is with prejudice except as to the Plaintiffs' general negligence and derivative counts, and as to the Plaintiffs' Magnuson-Moss Warranty Act count, all of which may be repled in accordance with the rulings in this Order. The Retailer Defendants' Motion to Dismiss at docket entry 2044 and the Distributor Defendants' Motion to Dismiss at docket entry 2045 are **DENIED AS MOOT**.

[19] At the Hearing, the Defendants agreed that these motions would be moot, provided the Court granted their earlier motions on pre-emption grounds. DE 2499 at 124.

Under Pretrial Order # 36, the Plaintiffs' repled Master Complaints are due 30 days after the Court issues its Order on Article III standing. DE 1346 at 4. The Court **AMENDS** that requirement in Pretrial Order # 36. The Plaintiffs' repled Master Complaints are due 30 days after the Court issues its forthcoming Order on the Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. DE 1580. All other requirements in Pretrial Order # 36 remain in place.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 31st day of December, 2020.

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record